FEB - 7 2014

510(k) Summary

Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III)

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Submission Sponsor	Twin Star Medical, Inc. 700 South 10th Avenue, Suite 120 Minneapolis, MN 55415 Tel: 612-382-0888 Fax: 612-338-9181
Submission Consultant	Sachs & Associates, Inc. Gregory W. Sachs, President 5116 Birch Road Minnetonka, MN 55345 Tel: 612-840-1568 Fax: 952-931-0531
Date Prepared	January 15, 2014
Device Trade Name	Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III)
Device Common Name	Monitor, Pressure, Intracompartmental
Classification Name	Unclassified, Product Code LXC
Classification Panel	Orthopedic
Predicate Devices	Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II).
Intended use	The Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III) is intended for the immediate or continuous measurement of intracompartmental pressures and/or the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.
Device Description	The Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III) consists of four major components; an Introducer, a Pressure Monitoring and Fluid Collection (PMFC) Catheter, a Fluid Collection (FC) Catheter, and a Compartment Pressure Monitor. The Introducer consists of tear-away plastic sheath placed over a stainless steel trocar. The Introducer provides an access to the targeted muscle

	compartment to facilitate the placement of the indwelling Pressure Monitoring Fluid Collection / Fluid Collection catheter. The indwelling Catheter is designed to monitor intramuscular compartment pressure as well as provide a means to sample interstitial fluid for laboratory analysis. The indwelling Catheter is designed for use up to 24 hours. The Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III) provides a means of displaying the intracompartmental pressure.
Performance data	A risk assessment was conducted which covered (1) all aspects of the possible effects on the safety and effectiveness of the modified device, (b) described each device modification under consideration, (c) the verification and validation activities with acceptance criteria, (d) scientific justification for each activity and (e) acceptance criteria. Testing included ASTM 4169-09, Distribution Cycle 13, electrical safety (IEC 60601-1 – Medical Electrical Equipment Part 1: General Requirements for Safety 1988 + A1: 1991 + A2; 1995) and EMC Emissions and Immunity (IEC 60601-1-2:2001 + A1:2004 Ed. 2, Medical Electrical Equipment, Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests - Class A Radiated and Conducted Emissions and Immunity for Non Life-Supporting Equipment). Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
Summary of Substantial Equivalence	The Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III) utilizes substantially equivalent performance attributes and safety components as the predicate device. It shares the following similarities to the predicate device: • Monitoring Pressure • Electrical Safety • Vacuum Source • Principles of operation
Conclusion	Based on the similar indications for use, technological characteristics and performance testing, Twin Star Medical, Inc. believes the proposed device, the Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III), is substantially equivalent to the Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II, K090961).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Twin Star Medical Incorporated
% Mr. Gregory W. Sachs
Sachs & Associates Incorporated
5116 Birch Road
Minnetonka, Minnesota 55345

February 7, 2014

Re: K131966
Trade/Device Name: Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III)
Regulatory Class: Unclassified
Product Code: LXC
Dated: January 15, 2014
Received: January 16, 2014

Dear Mr. Sachs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131966

Device Name: Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III)

Indications for Use:

The Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III) is intended for the immediate or continuous measurement of intracompartmental pressures and/or the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003690S Date: 2014.02.07 07:18:51 -05'00' for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K131966